510 (k) SUMMARY

JAN 17 2013

This 510(k) summary of safety and effectiveness is submitted in accordance with all of the requirements
and follows Office of Device Evaluation guidance concerning the organization of a 510 (k) summary.

MED-Fibers Fiber Optic Laser Delivery System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

MED-Fibers, Inc.
2675 E. Bartlett Place
Chandler, AZ 85249
Phone: (480) 516 8454
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Contact Person: Dr. Armin Kaus, Ph.D.

Date Prepared: December 14, 2012

Name of Device and Name of Sponsor

MED-Fibers Surgical Laser Fibers

MED-Fibers, Inc.
2675 E. Bartlett Place
Chandler, AZ 85249

Common or Usual Name

Nd:YAG-, Ho:YAG-, KTP- and Diode Laser – Fiber Optic Laser Delivery Systems

Classification Name

Surgical Laser Accessory
Regulation: **21 CFR §878.4810**
Classification: **II**
Product Code: **GEX**

Predicate Devices

Laser Peripherals Bare Fibers	**(K972272)**
Laser Peripherals Reusable Bare Fibers	**(K011207)**
FiberTech (LEONI) Bare Fibers (single and reusable)	**(K050738)**
Lumenis SlimLineEZ Fiber Delivery Device	**(K011703)**
InnovaQuartz (AMS) Sure Flex Laser Fiber	**(K050108)**
CeramOptec MegaBeam Fiber Laser Delivery Systems	**(K934008, K943445, K943444, K943526, K943527, K941909)**
BioLitec Radial Emitting shaped Fiber Optic delivery System	**(K110080)**
BioLitec MegaBeam Endo-ENT-Probe	**(K113858)**
BioLitec MegaBeam Endocular- and Aspirating Endo Probe	**(K113792)**
BARD Medical Holmium Laser Fibers	**(K120926)**
Fiberoptic Fabrications Laser Delivery System	**(K120810)**
Cynosure SideLaze800 Side Fire Firing Laser delivery device	**(K121127)**

Intended Use / Indications of Use

The MED-Fibers, surgical fiber optic laser delivery device, Endo-ENT fibers, Side Fire Laser delivery fibers and Endo Probes including Aspirating Endo Probes are intended for delivery of laser light to soft tissue in the contact and non-contact mode during surgical procedures including via endoscopes and cystoscopes. The MED-Fibers surgical fiber optic laser delivery device is intended for use with any cleared surgical laser with a SMA 905 or SMA 905 compatible connectors. In addition cleared lasers with SMA 906 connectors.
The MED-Fibers surgical fiber optic laser delivery devices are indicated for use in general surgery applications for: incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in a contact or non contact mode. It is also indicated for use in open or closed endoscopic applications where incision, excision, tissue dissection, excision of external tumors

and lesions, complete or partial resection of internal organs, tumors or lesions, tissue vaporization, hemostasis and or coagulation may be indicated.
MED-Fibers, surgical fiber optic laser delivery devices is also intended as an aid for otologic procedures, for use in incision, excision, coagulation and vaporization of soft and fibrous tissue including osseous tissue. MED-Fibers surgical fiber optic delivery devices are also intended for intraocular photocoagulation with or without simultaneous aspirating/irrigating as an adjunct to vitrectomy surgery. Specific indications include the treatment of proliferative vitreoretinopathy, Tractional retinal detachments, proliferative diabetic retinopathy and various vascular tumors. MED-Fibers surgical fiber optic delivery device is also indicated for use in lithotripsy with a compatible laser cleared for the desired application. It is indicated for use with Argon, KTP/532, Ho;YAG, Nd;YAG, 1.44YAG and Diode Lasers (532nm – 2100nm) with peak and continuous power from 1 – 300 Watt. MED-Fibers surgical laser fibers is indicated for use in general surgery, urology, gastroenterology, gynecology, dermatology, vascular surgery, neurosurgery, plastic surgery, ENT/otolaryngology, endovenous occlusion of the greater saphenous vein in the patient with superficial vein reflux and laser assisted lipolysis with an approved compatible laser marketed for use in the desired application.

Technical Characteristics

MED-Fibers surgical laser delivery system fibers contains the same components and the same technological characteristics as the predicate devices. The fiber core and cladding or fibers with no cladding are made from silica which is the same material used in all the predicate devices. As mentioned, the optical fiber is made out of silica with a coaxially mounted protective sheath. The fiber distal tip can be several configurations and the fiber can be used with hand pieces.
MED-Fibers surgical laser delivery system fibers has no differences in technology and as such does not raise any new questions on safety or efficacy. Various core diameter sizes (200, 272, 365, 550, 600, 800 and 1000 microns) are offered.

Performance Data

The performance of the MED-Fibers surgical laser fiber delivery systems is well established and documented so no performance testing is included. The MED-Fibers surgical laser fiber delivery system operates in the same manner as the predicate devices and performs with no difference as compared with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Med-Fibers, Incorporated
% Armin Kaus, Ph.D.
President/Chief Executive Officer
2675 East Bartlett Place
Chandler, Arizona 85249

January 17, 2013

Re: K124003
Trade/Device Name: MED-Fibers Surgical Laser Fibers
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: December 20, 2012
Received: December 26, 2012

Dear Dr. Kaus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K124003

Indication of Use Statement

5IO(k) Number (if known): ____K _____

Device Name: MED-Fibers Surgical Laser Fibers

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MED-Fibers, surgical fiber optic laser delivery devices is also intended as an aid for otologic procedures, for use in incision, excision, coagulation and vaporization of soft and fibrous tissue including osseous tissue (Diode Laser 532nm-2100nm). MED-Fibers surgical fiber optic delivery devices are also intended for intraocular photocoagulation with or without simultaneous aspirating/irrigating as an adjunct to vitrectomy surgery. (Diode Laser 532nm-2100nm), Specific indications include the treatment of proliferative vitreoretinopathy, Tractional retinal detachments, proliferative diabetic retinopathy and various vascular tumors (Diode Laser 532nm-2100nm)

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Prescription Use __X__ (Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use (21. C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.01.16 15:45:09 -05'00'

(Division Sign-Off) for mkm

Division of Surgical Devices

510(k) Number K124003